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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,343	01/31/2001	John T. McDevitt	5119-00529/EBM	7209

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/775,343

Applicant(s)

MCDEVITT ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 309,311-321,323,324 and 326-341 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 309,311-321,323,324 and 326-341 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **FINAL ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 13 October 2005 in which claims 309, 329 and 330 were amended, claim 325 was canceled, claim 341 was added and Terminal Disclaimers were filed. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 3 June 2005 are withdrawn in view of the amendments and Terminal Disclaimers. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by amendment, are discussed.

Claims 309, 311-321, 323-324 and 326-341 are under prosecution.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 309, 311-319, 323, 326, 330, 332-335, 337-339 and 341 are rejected under 35 U.S.C. 102(e) as being anticipated by Grow (U.S. Patent No. 5,866,430, issued 2 February 1999).

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Regarding Claim 309, Grow discloses a system comprising a body, a light source disposed within the body, a cartridge (#55), wherein the cartridge is removable and positionable within the body (Column 38, line 64-Column 39, line 15), wherein the cartridge comprises a body (#56) and a sensor array (tape, filter or support Column 39, lines 1-61, Fig. 3) wherein the array comprises a supporting member and at least one cavity (interior space of the cassette as illustrated in Fig. 3) within the supporting member, a polymeric bead particle positioned in the cavity and having a receptor bound thereto (i.e. receptor bioconcentrator, Column 19, lines 54-64 wherein the bioconcentrator is immobilized on a support e.g. bead, Column 21, lines 10-28), and a detector disposed within the body configured to detect a single from analyte interaction such that the light source and the detector are positioned such that light passes from the light source to the particle and onto the detector (Fig. 1 and Column 36, line 54-Column 37, line 67).

Regarding Claim 311, Grow discloses the system further comprising a sample input port positioned on the body and coupled to the sensor i.e. inlet side (Column 39, lines 1-15).

Regarding Claim 313, Grow discloses the system further comprising a sample input port and filter positioned on the body and coupled to the sensor (Column 39, lines 1-15).

Regarding Claim 314, Grow discloses the system further comprising a fluid cartridge coupled to the body and array i.e. liquid pump #25 (Column 37, lines 20-27).

Regarding Claim 315, Grow discloses the system further comprising an electronic controller disposed in the body and coupled to the sensor, light source and detector (Column 37, lines 1-14)

Regarding Claim 317, Grow discloses the system further comprising a data transfer system e.g. computer (Column 37, lines 1-14).

Regarding Claim 318 Grow discloses the system wherein the detector comprises a monochrome detector (Column 2, lines 40-45).

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Regarding Claim 319 Grow discloses the system wherein the detector comprises a color detector (Column 55, lines 5-28).

Regarding Claim 323, Grow discloses the system comprising a fluid delivery system e.g. pump (Column 37, lines 20-25).

Regarding Claim 326, Grow discloses the system comprising a plurality of particles that are detected simultaneously (Column 21, lines 29-51).

Regarding Claim 330, Grow discloses the system wherein the particles are associated with a signal displaced and detected upon analyte binding i.e. scattering spectral bands (Abstract).

Regarding Claim 332, Grow discloses the system further comprising channels for flowing fluid into and away from the cavity (Column 60, lines 29-47).

Regarding Claim 333, Grow discloses the system wherein the supporting member further comprises a barrier layer over the cavity to inhibit dislodgement of the particle (i.e. cassette cover and sample window, Column 39, lines 1-15 and Fig. 3).

Regarding Claim 334, Grow discloses the wherein the supporting member further comprises a barrier layer over the cavity to inhibit dislodgement of the particle (i.e. cassette cover and sample window, Column 39, lines 1-15 and Fig. 3) and a channel is formed for fluid flow between the barrier and support (Column 60, lines 29-47).

Regarding Claim 335, Grow discloses the supporting member comprises plastic (Column 21, lines 20-28).

Regarding Claim 337, Grow discloses the system wherein the cavity is configured such that fluid passes through the cavity (Column 60, lines 29-47, Fig. 1).

Regarding Claim 338, Grow discloses the system further comprising a pump coupled to the supporting member (Column 37, lines 20-25).

Regarding Claim 339, Grow discloses the system wherein a channel is formed in the supporting member coupled to a pump (Column 60, lines 29-47, Fig. 1).

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Regarding Claim 341, Grow discloses the system wherein the array is positioned within a removable cartridge (Column 38, line 64-Column 39, line 15 and Fig. 3).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 324, 327-329, 331 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grow (U.S. Patent No. 5,866,430, issued 2 February 1999) in view of Lavigne et al (J. Amer. Chem. Soc. 1998, 120: 6429-6430).

Regarding Claim 324, 327-329, 331, Grow discloses a system comprising a body, a light source disposed within the body, a cartridge (#55), wherein the cartridge is removable and positionable within the body as detailed above (Column 38, line 64-Column 39, line 15). Grow does not teach light emitting diode light source (claims 320-321), a charged-coupled device detector (324), swelling particles of between 0.05 and 500 microns (Claims 327-329) or silicon support (Claim 331).

However, Lavigne et al teach a similar a multi-component device comprising silicon wafers having cavities for particle-immobilized receptors wherein the particles of between 0.05 and 100microns swell to fit the cavity, bead color change is detected upon analyte binding using CCD (Fig. 1-2 and page 6429, right column through page 6430). Lavigne et al further teach the multi-components of their micromachined device function together to provide a powerful tool for the detection of multiple analytes simultaneously (page 6430, last paragraph). It would have been obvious to one of ordinary skill in the art at the time the claimed invention

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was made to modify the device of Grow with the light source, detector, and beads of Lavigne et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of efficient detection of multiple analytes simultaneously as taught by Lavigne et al (page 6430, last paragraph).

6. Claims 320, 321 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grow (U.S. Patent No. 5,866,430, issued 2 February 1999).

Regarding Claims 320-321, Grow discloses the system comprising a cartridge having a support wherein the sample is "drawn through" the cartridge using a liquid pump (#25) (Column 37, lines 20-24). While Grow does not define the pump as a vacuum, the fact that the pump functions to draw the sample into the cartridge, clearly suggests that the pump functions as a vacuum. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize a vacuum as a pump in the device of Grow based on the desire to draw the sample into and through the device.

7. Claim 336 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grow (U.S. Patent No. 5,866,430, issued 2 February 1999) in view of Drexler (U.S. Patent No. 4,588,665, issued 13 May 1986).

Regarding Claim 336, Grow discloses the system comprising a cartridge comprising a support disposed within a body wherein the support comprises a bar code for identification of biomolecule on the support (Column 39, lines 62-67). Grow does not specifically teach bar code composition. However, it was well known at the time the claimed invention was made

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that bar codes are recorded of photoresist material as taught by Drexler (Column 1, lines 40-49). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the photoresist of Drexler to the support of Grow. One of ordinary skill in the art would have been motivated to do so based on the well-know material and method for mass data storage as taught by Drexler (Column 1, lines 40-49).

8. Claim 340 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grow (U.S. Patent No. 5,866,430, issued 2 February 1999) in view of Wang et al (U.S. Patent No. 5,804,451, issued 8 September 1998).

Regarding Claim 340, Grow discloses the system comprising a light source disposed within a body. Grow does not specifically teach the light source comprises a light emitting diode. However, Grow does teach that any light source suitable for generating Raman spectral information is usable within their device (Column 21, lines 52-56). Wang et al teach the light diodes are preferred light source for Raman detection because they can be employed with reduced cost and size (Column 6, lines 14-26). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the diode light source of Wang et al to the device of Grow. One of ordinary skill in the art would have been motivated to do so based on the suggestion of Grow (Column 21, lines 52-56) and further based on their reduced cost and size as desired in the art as taught by Wang et al (Column 6, lines 14-26).



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9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### **Conclusion**

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

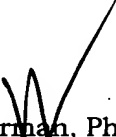
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
December 27, 2005